DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

93455d

August 12, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 – 37

Charles W. Herbster
President/CEO/CFO/COB
Conklin Company, Inc.
551 Valley Park Drive
Shakopee, Minnesota 55379

Dear Mr. Herbster:

During the Food and Drug Administration's (FDA) inspection of your firm conducted on April 24-25, 2001, June 5-6, 2002, June 28, 2002, and July 8, 2002, our investigators found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) concerning the marketing of various products. These products include Life Track™ Arthritis & Joint Support, Cold Season Formula, Vitamin E, Multi Mineral, Vitamin C, Vitamin B-Complex, Multi-Vitamin, and Bone Support. You can find the Act and the food, drug, and dietary supplement labeling regulations through links in the FDA's world wide web home page at http://www.fda.gov.

The name of the Life Track™ Arthritis & Joint Support product suggests that the product is intended for use as a drug to treat arthritis. Because this labeling suggests that this product is intended to be used in the cure, mitigation, treatment or prevention of disease, this product is a drug within the meaning of Section 201(g) of the Act. We are unaware of any scientific evidence that demonstrates that this drug is generally recognized as safe and effective for the treatment of arthritis. Therefore, this product is an unapproved new drug under Section 201(p) and cannot be legally marketed without an approved new drug application under Section 505(a) of the Act. You were previously advised of this violation of the Act. FDA sent a letter, dated September 23, 1998, to your company (Ms. Linda M. Gearke, Manager, Family Care Product Division), which specifically advised your company that inclusion of the term "arthritis" in this product's labeling suggested that the product was intended to be used as a drug rather than a dietary

supplement. Despite this letter, your company continued to sell this product with the term "arthritis" included in the label.

This drug is also misbranded because its labeling fails to bear adequate directions for treatment of the condition for which it is offered [Section 502(f)(1) of the Act] and its labeling is false and misleading because it suggests that this product is safe and effective for its intended use when, in fact, this claim has not been established [Section 502(a) of the Act].

The name of the Life Track™ Cold Season Formula product also implies it is intended for use as a drug (the prevention and treatment of cold). As discussed above for the Arthritis and Joint Support product, because this product's labeling represents and suggests that it is intended to be used in the cure, mitigation, treatment or prevention of disease, this product is a drug within the meaning of Section 201(g) of the Act. Since we are unaware of any scientific evidence that demonstrates that Life Track Cold Season Formula is generally recognized as safe and effective for the prevention and treatment of cold, it is, therefore, an unapproved new drug under Section 201(p) and cannot be legally marketed without an approved new drug application under Section 505(a) of the Act.

The Life Track™ Vitamin E, Multi Mineral, Vitamin C, Vitamin B-Complex, Multi Vitamin, and Bone Support products are misbranded within the meaning of Section 403(q)(5)(F) of the Act in that these labels fail to bear the Supplement Facts panel which is required under Title 21, Code of Federal Regulations, Part 101.36 (21 CFR 101.36), and are not exempt from this requirement. In addition, these products are misbranded within the meaning of Section 403(s)(2)(B) of the Act in that the labels fail to identify the product using the term "dietary supplement" [21 CFR 101.3(g)], or other alternative descriptive term authorized by regulation.

The violations of the Act described above are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with applicable legal requirements. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within 15 working days of receiving this letter. Your response should describe the specific actions you will take, or have taken, to correct the noted violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If

corrective action cannot be completed within 15 working days, please state the reason for the delay and time within which corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the above address.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl